

## **II. RESPONSE TO OFFICE ACTION**

### **A. Status of the Claims**

Claims 39, 40, 46, 47, 63-66, 68-83, and 88 were pending. Claims 39, 40, 63-66, 68-70, 73-83 and 88 were rejected by the Office Action. Claims 46, 47, 71, and 72 were objected to. No amendments have been made, therefore claims 39, 40, 46, 47, 63-66, 68-83, and 88 are pending.

### **B. New Rejections**

Applicants note that the Action raised new rejections under 35 U.S.C. § 112, first paragraph, after the Applicants adopted the Examiner's suggestions for amending the claims to overcome all of the previous rejections. Applicants further note that these rejections were not made in response to the amendments and that this application has been pending since 2001. Applicants sincerely hope that the merits of this case will be considered fairly and efficiently to avoid further delay in securing valid patent protection for the Applicants' invention.

#### **1. Claims 39, 40, 63-66, 68-70, 73-83, and 88 Are Adequately Described**

The Action rejects claims 39, 40, 63-66, 68-70, 73-83, and 88 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It contends that the claims encompass methods that require assaying Fortilin polypeptide activity *in vitro* or in a cell and that the claims encompass a genus of Fortilin activities of indeterminate size. The Action further argues that the specification says that Fortilin binds p53 and it binds MCL1 polypeptide and that because no other activities are found in the prior art, the skilled artisan cannot envision any other activity encompassed by the claims. Applicants respectfully traverse this rejection.

Applicants note that the Written Description Guidelines indicate there is a **“strong presumption** that an adequate description of the claimed invention is present in the specification

as filed.” Guidelines for the Examination of Patent Applications Under 35 U.S.C. §112, ¶ 1, “Written Description” Requirement at II.A (emphasis added). Moreover, patent law states that the Examiner has the initial burden of presenting evidence or reasons for an inadequate written description requirement. *See In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976). Additionally, “an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.” *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336 (Fed. Cir. 2001).

The Action admits that the specification teaches that Fortilin promotes apoptosis. There is no basis in the written description requirement that the Applicant needs to describe the mechanism by which this occurs or the different pathways involved in these processes.

Moreover, the basis for the rejection is the unsupported allegation that the method claims recite “Fortilin activity,” which refers to a genus of activity. The Action acknowledges that Fortilin activity is provided in that the specification describes that Fortilin induces apoptosis, that it binds to p53, and that it binds MCL1. There is no evidence or any indication of *other* activities of Fortilin to support the contention that there are activities of Fortilin not described. It cannot be sufficient to make a rejection based on a completely hypothetical situation—that there *may be* other activities of Fortilin.

In addition, the specification describes two particular ways in which Fortilin activity may be evaluated based on its binding activity. The specification discloses that Fortilin has the ability to bind p53 and MCL1 and each of those interactions provides a further basis for evaluating Fortilin activity. Even if there were other activities of Fortilin, the specification describes a representative number of species to describe the putative genus of Fortilin activities.

For the foregoing reasons, the written description rejection is without merit and Applicants respectfully request that it be withdrawn.

## 2. Claims 39, 40, 63-66, 68-70, 73-83, and 88 Are Enabled

The Action rejects claims 39, 40, 63-66, 68-70, 73-83, and 88 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The grounds for this rejection are similar to the grounds asserted for the written description rejection. Essentially, the Action that the claims encompass methods that require assaying Fortilin polypeptide activity *in vitro* or in a cell and that the claims encompass a genus of Fortilin activities of indeterminate size. The Action further argues that full scope of the claims would require undue experimentation to practice because the specification teaches only that Fortilin binds p53 and it binds MCL1 polypeptide. Applicants respectfully traverse this rejection.

Applicants have described a method involving measuring Fortilin activity (*i.e.*, apoptosis) and they have described how this can be achieved in their specification, for instance, in Examples 3 and 8. In addition, the skilled person could use p53 binding or MCL1 binding to evaluate Fortilin activity.

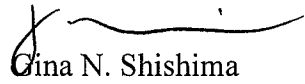
Furthermore, methods for measuring apoptosis and binding were well known to those of skill in the art at the time the application was filed. “The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available in the public.” MPEP 2164.05(a) (citing *inter alia*, *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q. 2d 1331, 1332 (Fed. Cir. 1991)). Consequently, it cannot be alleged that it would require undue experimentation to practice the invention. The Action provides no evidence either from the specification or art that even suggests Fortilin may have other activities. That the skilled artisan would have to practice undue experimentation to determine whether Fortilin has *other* activities is without any basis in the law. Accordingly, Applicants respectfully request that this rejection be withdrawn.

### CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.

Should the Examiner have any questions or comments or identify any issues that can be readily addressed in a conversation with Applicants' representative, I request that he please contact me at 512-536-3081.

Respectfully submitted,



Gina N. Shishima  
Reg. No. 45,104  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 474-5201  
(512) 536-4598 (facsimile)  
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